

(f) a [solubizing] solubilizing agent for the oil-soluble ingredients; and,

(g) an emulsifying agent for mixing the oil phase with the aqueous phase.

10. (Amended) The oil-in-water emulsion of Claim 1 which has been converted to a gel consistency by the incorporation of a gelling agent selected from one of methoxycellulose, ethoxycellulose, carboxycellulose, acrylamide, polyvinylpyrrolidone, or [chitosan] chitosan.

11. (Amended) The oil-in-water emulsion of Claim 1 wherein the [bioflavonoid] oligomeric proanthocyanidins are included.

#### **REMARKS**

At the outset, the thrust of the present invention bears repeating. According to the present invention, a treatment protocol for the cosmetic condition in females, commonly known as cellulite, involves novel utilization of the following inter-related physiological precepts.

Estrogen can be inhibited by blocking estrogen receptors (ER) located on the fibroblast cells with a selected isoflavone, like genistein. Collagen fibers form a tough fibrous tissue termed the fascia, which hold fatty tissues in discrete compartments. Collagenase breaks down collagen fibers. The action of collagenase can be blocked at the level of collagen by employing proanthocyanidins. The production of estrogen from testosterone can be blocked by another isoflavone like genistein. This isoflavone also blocks the initiation of preadipocytes by estrogen, to form fully-differentiated adipocytes, thus inhibiting the expansion of fat mass. Fat tissue may also be reduced by stimulating the formation of cyclic adenosine triphosphate (cAMP), which cause the activation of lipase on fatty tissue, with coleus forskohlii serving as an effective stimulator of cAMP. The xanthine and theophylline acetate, inhibit the enzymatic action of phosphodiesterase, which destroy a cAMP, thus prolonging the lipase stimulating action of cAMP. Finally, a cofactor like acetyl carnitine is employed to increase the metabolism of the released free fatty acids by the mitochondria. The protocol is foreign to the citations.

The Examiner proposed typo corrections to Claims 1, 10, and 11, are set forth above. Once approved by the Examiner, they form Attachment A in clean copy as well. The objection to the recitation of the "bioflavonoid oligomeric proanthocyanidins" is respectfully acknowledged, by deletion of the superfluous term "bioflavonoid."

The original 11 claims were rejected under Patent Code §103(a) based on a shotgun

(varied) reliance on four U.S. patents Soudant, Majeed, Sekiya, and Koulbanis, two foreign patent documents (Lotte and DeSimone), and two non-patent documents (Kuppusamy and Gennaro), for a total of eight citations.

Broadly, the Examiner has asserted a hindsight reconstruction from scattered citations in seeking to effect a teaching or suggestion of the claimed multicomponent formulation of the present invention. The suggestion to combine elements found in the prior art must come from the Applicant himself, rejections born of hindsight are improper. *Panduit Corp. v. Dennison*, 774 Fed. 2d 1082, 1091-92, (CAFC 1985). It is basic patent law that if a prima facie obviousness, the teachings of references can be combined only if there is some suggestion or incentive to do so. (*ACS Hosp. Sys. v. Montefiore Hospital*, 732 Fd. 1572, 1577 (CAFC 1984).

Also, there must be some reason, suggestion, or motivation found in the prior art, whereby a person of ordinary skill in the field, would make that combination. *In re: Octiker*, 977 Fd. 1443, 1447) CAFC 1992).

In the PTO action, page 3/4, the Examiner notes what elements are common to the present claims that the citations do teach or suggest. In PTO action page 4, she concedes that several of the recited elements in the examined claims are neither taught, or let alone suggested. The Applicant will now set forth what other features and motivations that each of the citations lack; and what law preclude the picking and choosing of elements for a proscribed force-fitting of these disparate references in striving to meet the here-claimed recitations.

Soudant '230 teaches a topical emulsion composition containing lipolytic agents, like caffeine and a carnitine. It makes neither a mention or suggestion for use of an isoflavone, a hydroxyflavone, a plant extract that stimulates the action of cyclic AMP, any other bioflavanoids, or capillary protectants, all of which are presently taught and comprise components of the claimed formulation.

While Majeed '596 addresses a method of promoting lean body mass, and treating of a mood disorder by administering internally an effective amount of forskolin, it does not even recognize the special biological phenomenon of female cellulite. It surely does not suggest c. forskohlin for inclusion in any topical formulation for treating that cosmetic disorder in women. So there is no motivation or incentive here to consider forskoilli in the present setting.

While the Lotte Abstract speaks to lipase inhibitors containing flavanoid compounds as active agents, to be used in food and drink, only quercetin of the hydroflavones is taught as useful, when combined with Mcilvane buffer (a complex oleate and swine spleen lipase), for oral ingestion. Again, there is no mention of human cellulite, or any suggestion of possible utility in a topical, extended term treatment using this hydroxyflavone, inter alia, biochemical compounds.

The Kuppusamy article (1992) is directed to the effects of flavanoids on cyclic AMP and phosphodiesterase on lipids in rat adipocytes. It lists quercetin and fisetin among the 31 flavanoids tested. As to these two flavanoids, they showed a dose-and-time dependent increase in lipolysis which was synergistic with epinephrine. However, there is no teaching here of such flavanoids as candidate compositions for topical treatment of cellulite, which includes an isoflavone, like genistein or diadzein; and acetyl; L-carnitine to move the fatty acids; a plant extract like coleus F; or other bioflavanoids as capillary protectants. The reference-cited hydroxyflavones are merely two species of the several compounds of the here claimed formulations. They are not remotely suggested for such an anti-cellulite evaluation by the Kuppusamy technical paper.

Sekiya '906 is directed to a method of promoting fat degradation in fat cells by orally, or by injection, of a selected isoflavone to a human subject. The basis for this is solely on invitro data with preadipocyte (a fat cell precursor). While either genistein, diadzin or daidzein, or diazeine were tested, and optional with customary inert additives, like bulky agents and excipients included, the selected isoflavones were to be used alone. There is neither a teaching or suggestion here of the use of a topical formulation wherein the hydroxyflavone, a xanthine derivative, and acetyl carnitine, a plant extract like c. Forskohli, and capillary protectant are combined into a useful composition for topical treatment of cellulite. Consequently, while Sekiya is related technology, it lacks any motivation to alter its precise isoflavones so as to be blended with the more complex formulations of the present invention.

Koulbanis '043 is to cosmetic compositions having in combination, a thioether, and a xanthine derivative, applied topically with massage, or by using trans-cutaneous electrophoresis. The patent exemplification is limited to caffeine and theophylline, "an anti-cellulitis" solutions. No other active composition are taught or suggested. The patent is directed to massage or using

transcutaneous electrophoresis. As to the "slimming" action, only example VII goes to that, and the recited "cream" formulation employs no enzymes or flavanoids, at all.

The DeSimone PCT international patent specification teaches the use of L-acetyl carnitines, among other carnitines, for the treatment of cytological disorders related to IGF-I (insulin-like growth factor). This shotgun disclosure is directed to numerous pathologies (see claim 2 for a long list of them), with only obesity having the remotest connection to the female cellulite. There is no suggestion of any other active principals, in fact, not of the isoflavones, hydroxyflavones, xanthine, plant extract, and so forth. The reference focuses solely on carnitine derivatives and in no way relates to the formulation of the present invention directed to treatment of cellulite

Lastly, the Examiner would invoke the Gennaro text for the proposition that methyl cellulose and carrageenan are useful as gelling agents, an observation with which Applicant does not take issue. The recitation of these inert ingredients in dependent claim 9 is not presented as being an independent invention. Rather, it goes to reciting preferred formulations. It is statutory law that these dependent claims incorporate all of the recitations of the independent claims from which they depend.

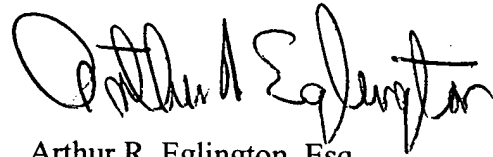
By way of augmentation of the Specification, in teaching the testing of candidate active entities described in the formulas, a showing from this Applicant under 37 C.F.R. Section 1.68 and 1.132 is submitted herewith. This showing comprises quantifiable clinical evidence that the leading active components, like genistein, diadzein, and quercetin, when incorporated into topical emulsions will produce an appreciable reduction in fat infiltration, increase connective tissues, and effect a cosmetic improvement in the appearance of the buttocks.

The Examiner's allegation that it would have been obvious when the invention was made to employ all the actives together in one composition or method is untenable. Most of the citation is focused on narrowed human conditions if at all, or teach only one or two active principles for a clinical effect. To meet even the terms of the oral-in-water emulsion of claim 1 for topical use, the Examiner has resorted to at least four different publications, each of which does not provide motivation for it's dissection and reconstitution in a novel context. Indeed, it can be argued that certain of these citations teach away from the present formulations, which thus undermines prima facie obviousness. Cf. *In re: Spinnable*, 405 Fd 2d 578, 587 (CCPA 1969). A reference teaches a way when a person of ordinary skill would be led in direction divergent from that of the path taken by the Applicant here.

By way of example, Soudant, Majeed, Lotte, Sekiya, and DeSimone are all directed to treatments for other human problems, like the varied manifestations of obesity. None, save Koulbanis, even speak to anti-cellulite action. The contrived cutting and pasting of the several citations is untenable in the law, and should be withdrawn upon fresh reconsideration in light of these extended remarks. The allowance of the slightly amended original set of claims 1-11, is courteously solicited.

Lastly, the enclosed Rule 132 Declaration establishes that representative flavones are capable of inhibiting the undesirable destructive effects of estrogen on connective tissue and thus provide a positive effect on treating cellulite.

Very truly yours,



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Date: 30 May 2002  
Enclosure: Pat. R. 132  
Declaration of P.T. Pugliese

